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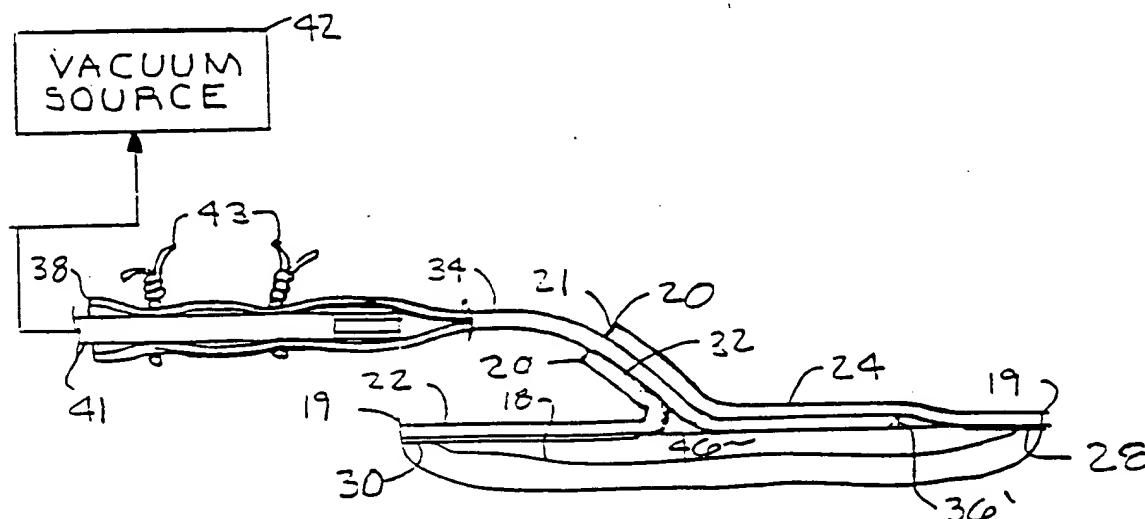
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(54) Title: FLUIDIC CONNECTION SYSTEM AND METHOD



(57) Abstract

A wound dressing (10) includes a cover membrane (22) comprising a semi-permeable material with an adhesive-coated (30) skin contact surface (28). An opening (32) is formed in an interior portion of the membrane. An intermediate layer of material may be placed between the wound and the membrane contact surface for either absorbing fluids from the wound, e.g. with a hydrocolloid or hydrophilic material, or for passing such fluids to the opening with a synthetic material, e.g. rayon. A tube (34) includes a proximate end (36) fluidically communicating with the wound through the membrane opening. A distal end (38) of the tube is adapted for connection to a suction source (47) for draining the wound or a fluid source for introducing liquid medication to the wound. Both aspiration and introduction can be either active or passive. A wound treatment method is also disclosed.

FLUIDIC CONNECTION SYSTEM AND METHODCross-Reference to Related Application

Continuation-in-Part of U. S. Patent Application Serial
Number 07/332,699, filed April 3, 1989.

Background of the Invention1. Field of the Invention.

The present invention relates generally to fluidic connection systems, and in particular to systems for draining liquids from and introducing liquids to patients.

2. Description of the Relevant Art.

Various types of fluidic connection systems have heretofore been devised to meet the requirements of particular applications. In the medical field, fluidic connection systems find many applications, including wound dressings and systems for introducing fluids to and removing fluids from patients.

Wound dressings are typically applied over various types of wounds to promote healing and to reduce the risk of infection. Although various types of dressing materials have been successfully employed, membranes comprising semi-permeable materials are often preferred because they can increase patient comfort and lower the risk of infection. Semi-permeable membranes generally pass moisture vapors, but are generally impervious to liquids. Thus, they can promote healing by permitting a wound site to "breathe".

1 who are incontinent or have otherwise lost voluntary control
2 of their bladder functions, e.g. a paraplegic with a spastic
3 bladder condition. However, patients fitted with urethral
4 catheters are often subjected to risks of bladder and
5 urinary tract infections.

6 To avoid some of these infection risks, condom
7 catheters have been devised which typically include a body
8 for placement over the penis and a bellows-type distal end
9 for resisting kinks and for connection to a drain tube.
10 However, condom catheters are susceptible to slippage and
11 can be difficult to maintain in place unless they are taped
12 to the patient's penis. Furthermore, there can be
13 difficulties in effectively draining sudden surges of urine,
14 which often back up and cause leakage problems.

15 Heretofore there has not been available a fluidic
16 connection system and method with the advantages and
17 features of the present invention.

18

19 Summary of the Invention

20

21 In the practice of the present invention, a fluidic
22 connection system is provided which includes a semi-
23 permeable membrane including a pair of panels each having a
24 perimeter and an edge strip. The membrane is formed by
25 connecting the panel edge strips together to form a seam
26 extending transversely across the membrane. The panels and
27 the membrane include inner and outer surfaces. A tube
28 opening extends through the seam between the panel edge

29

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1 membrane. Fluids from a draining wound can be evacuated
2 through the tube and liquid medication and irrigation can be
3 introduced through the tube to the wound site. The fluid
4 evacuation and introduction steps of the method can each be
5 accomplished both actively and passively, and can be
6 alternated in a wound treatment procedure. Additional steps
7 that can be included in the method of the present invention
8 include extending an inner conduit through the sheath and
9 sealing the inner conduit and the sheath together in a
10 fluid-tight engagement.

11

12 Objects and Advantages of the Preferred Embodiments

13

14 The principle objects and advantages of the present
15 invention include: to provide a wound dressing; to provide
16 such a dressing which promotes the evacuation of drainage
17 fluids; to provide such a dressing which permits the
18 introduction of liquid medications; to provide such a
19 dressing which includes a semi-permeable membrane for
20 releaseable, adhesive attachment to the skin surface
21 surrounding a wound; to provide such a dressing which
22 protects against infection; to provide such a dressing which
23 promotes healing; to provide such a dressing which is
24 economical to manufacture, efficient in operation, capable
25 of a long operating life and particularly well adapted for
26 the proposed usage thereof; to provide a wound treatment
27 method; to provide a fluidic connection system and method;
28 to provide such a connection system and method which are
29 adaptable to various applications; to provide such a
30 connection system and method which can be utilized as a

1 Fig. 6 is an enlarged, fragmentary, vertical, cross-
2 sectional view of the dressing, particularly showing the
3 tube connected to a vacuum source.

4 Fig. 7 is an enlarged, fragmentary, vertical, cross-
5 sectional view of the dressing, particularly showing a
6 resealable injection port mounted on a distal end of the
7 tube.

8 Fig. 8 is a top perspective view of a wound dressing
9 comprising a first modified embodiment of the present
10 invention.

11 Fig. 9 is a top plan view of a wound dressing
12 comprising a second modified embodiment of the present
13 invention with an intermediate material layer between the
14 wound site and a cover membrane.

15 Fig. 10 is an enlarged, fragmentary, vertical, cross-
16 sectional view of the second modified wound dressing
17 embodiment, taken generally along line 10-10 in Fig. 9.

18 Fig. 11 is a perspective view of a fluidic connection
19 system comprising a third modified embodiment of the present
20 invention, shown in combination with a drain conduit and
21 fluid connection vessel for use as a condom catheter and
22 urine collection system.

23 Fig. 12 is a top plan view of the connection system
24 being applied as a condom catheter.

25 Fig. 13 is an enlarged, vertical, cross-sectional view
26 of the connection system taken generally along line 13-13 in
27 Fig. 12.

28 Fig. 14 is an enlarged, fragmentary, vertical, cross-
29 sectional view of the connection system, particularly
30 showing a funnel end of an inner conduit.

1 Referring to the drawings in more detail, the reference
2 numeral 10 generally designates a wound dressing embodying
3 the present invention. The dressing 10 is adapted for
4 protecting and treating a variety of wounds, such as that
5 shown at 12. Without limitation on the generality of the
6 useful applications of the present invention, the dressing
7 10 may be applied over burns, cuts, scrapes and ulcers of
8 various types, e.g. diabetic, decubitus, peripheral
9 vascular disease, venous stasis and trauma ulcers.

10 Skin ulcers are a common problem among many diabetics,
11 and are often brought on by poor blood circulation and nerve
12 damage associated with diabetes. The treatment of such
13 ulcers often involves grafting skin from a relatively
14 healthy donor site to an ulcerous wound site. Split
15 thickness surgical skin graft techniques may be employed to
16 obtain skin grafts from donor sites that can then heal
17 spontaneously. Full thickness skin grafts, on the other
18 hand, generally require closure of the donor site. It will
19 be appreciated from the following description that the wound
20 dressing and treatment method of the present invention is
21 particularly well adapted for the protection and
22 regeneration of skin graft donor sites by providing a single
23 dressing which facilitates both fluid drainage and growth
24 factor introduction.

25 The wound site 12 is surrounded by healthy skin 16. A
26 fibrin layer 18 forms at the wound site 12 from fibrinogen
27 by the action of thrombin and the clotting of blood (Figs.
28 2 and 6). Surgical wounds, including those associated with
29

1 A tube or sheath 34 includes a proximate end 36 located
2 under the membrane 22 and a distal or free end 38. The tube
3 34 can be inserted through the seam 21 which forms an
4 opening 32 between the panel edge strips 20 at approximately
5 the center of the membrane 22. A relatively short length of
6 the tube 34 adjacent to its proximate end 36 is shown under
7 the membrane 22, but greater lengths of the tube 34 could be
8 placed under the membrane 22. As shown in Fig. 5, the tube
9 proximate end 36 is open, and adjacent to the proximate end
10 36 an opening is formed. Preferably the tube opening 39
11 projects downwardly, i.e. away from the membrane skin
12 contact surface 28. The short length of the tube 34 which
13 is located under the membrane 22 can be releaseably secured
14 to the skin contact surface 28 by the adhesive coating 30,
15 preferably with the tube opening 39 facing downwardly.

16 The tube 34 can comprise, for example, a flexible,
17 plastic tube of the type that is commonly used as a
18 protective sheath for protection of sterility for
19 percutaneous intravenous catheter placement. Such sheaths
20 are commercially available from Aero International, Inc. of
21 Reading, Pennsylvania.

22 At its distal end 38, the tube 34 is adapted for: 1)
23 closure with a variety of suitable closure devices; 2)
24 connection to various active and passive fluid collection
25 devices for draining and evacuating fluid from the wound
26 site; and 3) connection to various fluid source devices for
27 actively and passively introducing fluid to the wound site.

28 Fig. 5 shows a bifurcated clip 40 for releaseably
29 closing and sealing the tube distal end 38, which is folded
30 upon itself as shown.

1 are commercially available for supplementing the bonding
2 action of the adhesive coating 30 in bonding the membrane
3 contact surface 28 to the healthy skin 16. The membranes 22
4 may be provided in various sizes to accomodate wounds of
5 different sizes. A sufficiently large membrane 22 should
6 normally be selected to provide ample overlap of the
7 perimeter 26 over the healthy skin 16 to insure a good bond
8 therebetween.

9 The tube distal end opening 39 may be placed directly
10 over the approximate center of the wound site 12, or it may
11 be placed eccentrically or at a depending location with
12 respect to the wound site 12. A dependent or lower position
13 for the opening 39 with respect to the wound site 12 may be
14 preferred to facilitate fluid drainage. The dressing 10 may
15 be applied promptly after a wound is inflicted, e.g.
16 immediately after the graft removal procedure and a skin
17 graft operation. To reduce the risk of infection, it may be
18 advisable to promptly cover the open wound site 12. The
19 wound dressing 10 may be kept in a sterile package until it
20 is needed. Such sterile packages and packaging techniques
21 are well known. For example, ethylene oxide may be used to
22 sterilize the dressing 10 prior to placement in a suitable
23 sterile package. The protective backing 23 is removed from
24 the membrane 22, thereby exposing its adhesive-coated
25 contact surface 28.

26 With the membrane 22 thus secured, a chamber 46 is
27 formed between the wound site 12 and the membrane contact
28 surface 28, and is surround by the membrane perimeter 26.
29 The chamber 46 fluidically communicates with the membrane
30 opening 32. In an evacuation mode of operation, such as

1 International, Inc. of Reading, Pennsylvania. Such
2 connecting devices are commonly used in connection with the
3 intravenous introduction of various liquid solutions.

4 In an active introduction mode of operation, solutions
5 may be pumped through the tube 34 into the chamber 46 for
6 application to the wound site 12.

7 The evacuation and introduction treatment steps can be
8 timed and sequenced as necessary to achieve the treatment
9 objectives. For example, treatment of a skin graft donor
10 site may involve fluid withdrawal and drainage for about two
11 days immediately following the skin graft operation,
12 followed by treatment steps comprising the introduction of
13 antibiotics and/or growth factor solutions to the wound
14 site. The evacuation and introduction steps can be
15 alternated, and the intervals between such steps can be
16 progressively increased or decreased as necessary to
17 facilitate healing. As the wound heals, progressively
18 smaller amounts of fluid will ooze therefrom and the
19 frequency and duration of the drainage operations can be
20 correspondingly reduced and finally discontinued altogether.

21 It will be appreciated that the wound dressing and
22 treatment method of the present invention are broadly
23 concerned with introducing fluid to wound sites and
24 evacuating fluid therefrom. The fluid introduction and
25 evacuation procedures described herein can be performed
26 indefinitely without having to change the dressing 10. The
27 tube 34 cooperates with the membrane 22 to permit the same
28 dressing 10 to be used for both procedures, which may be

29

30

1 altered as often as necessary. Infection risks and
2 patient discomfort can be reduced by minimizing wound
3 dressing changes.

4 The removal of toxins and bacteria from wounds is an
5 important aspect of the fluid drainage phase of the healing
6 process. The wound dressing of the present invention
7 facilitates removal of serum and other secretions to
8 minimize the risk of infecting the wound site and macerating
9 the tissue thereat. Growth factor solutions can be
10 important in promoting healing, and antibiotics can be
11 important in preventing and treating infection. Hence, a
12 comprehensive wound treatment can be implemented with the
13 wound dressing and treatment method of the present
14 invention.

15 The wound dressing 10 can be employed to irrigate a
16 wound whereby fluid is introduced and then removed.

17 The operation of the wound dressing 10 is largely a
18 matter of fluid mechanics, and the function of the wound
19 dressing 10 would probably be determined by such factors and
20 variables as: 1) fluid viscosity; 2) permeability of the
21 membrane 22; 3) cross-sectional area of the tube 34 and the
22 area of its opening 39; 4) the integrity of the seal around
23 the membrane perimeter 26; 5) the drawing power of the
24 suction or vacuum source 42; 6) coagulation of the serum or
25 other fluid; 7) the area of the fluid collection chamber 46;
26 8) the length of the tube 34; and 9) gravity and the
27 relative positions of various components. Naturally,
28 varying one or more of these factors or variables could
29 change the operation of the system. It is anticipated that,
30 applying such well-known principles of fluid mechanics, all

1 of the wound dressing components could be properly sized and
2 designed. For example, the tube opening 39 could be
3 enlarged, or multiple openings could be provided to increase
4 the rate of fluid flow into the tube 34. The rate of fluid
5 flow can further be increased by locating the tube distal
6 end 38 at a dependent area within the chamber 46, i.e. below
7 the level of most of the wound site 12. The tube 34 can
8 extend downwardly to a collection site below the level of
9 the wound site 12 to facilitate gravity drainage.

10 It is further anticipated that some fluids will resist
11 drainage because of their viscosities or because they tend
12 to coagulate. Drainage of such fluids can be effected by
13 irrigating the wound site 12.

14

15 IV. First Modified Embodiment 110

16

17 Figure 8 shows a wound dressing 110 comprising a
18 first modified embodiment of the present invention wherein a
19 relatively small membrane 122 is provided and functions as a
20 patch for a larger wound cover 115 with an opening 117 for
21 receiving a distal end 138 of a tube 134. The primary wound
22 cover 115 is selected to cover a wound site 112, and is
23 placed thereover in the normal fashion. The wound dressing
24 110 can be placed on the primary wound cover 115 in a
25 location chosen to enhance fluid introduction and/or
26 evacuation. For example, to enhance the evacuation of fluid
27 by gravity, it may be desirable to form the opening 117 at a
28 relatively low position of the wound site 112. Thus, fluid
29 will tend to flow to the tube 134 by gravity. To facility
30 the introduction and distribution of fluid, it may be

1 desirable to locate the wound dressing 110 at a relatively
2 high position on the wound cover 115. In fact, two or more
3 wound dressings 110 could be placed on a single, primary
4 wound cover 115, with a lower wound dressing 110 being
5 provided for fluid evacuation and an upper wound dressing
6 110 being provided for fluid introduction.

7 In the practice of the treatment method of the present
8 invention, the wound dressing 110 provides for considerable
9 flexibility in locating the wound dressing 110 in an
10 appropriate location on the wound site 112. After the
11 primary wound cover 115 is positioned, the opening 117 is
12 formed at the chosen location and the wound dressing 110 may
13 be applied, much like a patch, with the tube distal end 138
14 extending through the primary wound cover opening 117. It
15 will be appreciated that wound dressings 110 may be changed
16 as needed without changing the primary wound cover 115.

17

18 V. Second Modified Embodiment 210

19

20 A wound dressing 210 comprising a second modified
21 embodiment of the present invention is shown in Figs. 9 and
22 10 and includes an intermediate layer of material 250
23 between a wound site 212 and a cover membrane 222. The
24 intermediate material layer 250 can comprise a variety of
25 materials with varying properties such as: 1) absorbency; 2)
26 wicking or capillary action; and 3) surface contact action.
27 The intermediate material layer is primarily located in a
28 chamber 146 formed between the wound 212 and the membrane
29 222.

30

1 As a first example of an intermediate material layer
2 250, several hydrophilic colloid materials (i.e.
3 hydrocolloids) are available which would tend to absorb
4 fluids. For example, Envisan wound cleaning pads and paste
5 are available from Marion Laboratories, Inc. of Kansas City,
6 Missouri and comprise: spherical, hydrophilic Beads of
7 Dextranomer, 0.1 to 0.3mm in diameter; polyethylene glycol
8 3000 in the pad; polyethylene glycol 600; and water QS
9 enclosed in a polyamide net bag in the pad or available in a
10 metal foil packet for the paste. The Envisan dextramer
11 beads function to absorb fluid and facilitate healing by
12 drawing fluid from the wound. Excess fluid can be drained
13 from the intermediate material layer 250 to prolong its
14 effectiveness. Other hydrocolloids are commercially
15 available and may be employed with the wound dressing 210 of
16 the present invention, e.g. dextranimers available under the
17 trademark "Debrisan".

18 Alternatively, the intermediate material layer 250 can
19 comprise a mesh or sheet of synthetic material which is
20 generally nonabsorbent and would tend to wick fluid from the
21 wound site 212 to a tube distal end 238. For example, rayon
22 available under the trademark Owens non-adherent surgical
23 dressing from the Davis & Geck division of American Cyanamid
24 Company of Danbury, Connecticut could be used to form such
25 an intermediate material layer 250, and material available
26 from Marion Merrell Dow, Inc. of Kansas City, Missouri under
27 the trademark "Envinet" could also be employed. Such
28 materials may be referred to as "surface active", i.e.
29 promoting fibrin sealing on the wound surface. Such
30 materials can also satisfy a capillary purpose whereby fluid

1 be severed at the surface of the membrane, allowing the
2 closure patch 251 or a similar patch of the same material as
3 the wound dressing 10 to permanently seal the tube site.

4

5 VI. Third Modified Embodiment 310

6

7 A fluidic connection system 310 comprising a third
8 modified embodiment of the present invention is shown in
9 Figs. 11-16. Without limitation on the generality of useful
10 applications of the fluidic connection system 310, it is
11 shown in connection with a urine collection system 312 and
12 functions as a condom catheter. The connection system 310
13 generally includes a membrane assembly 314 and a tube
14 assembly 316.

15 The membrane assembly 314 includes a membrane 318 with
16 an inner or skin contact surface 320, an outer surface 322,
17 a perimeter 324 and an interior portion 326. As shown in
18 Fig. 11, the membrane 318 comprises first and second panels
19 328, 330.

20 The panels 328, 330 include inner contact surfaces 329,
21 outer surfaces 331, perimeters 333, and edges 335 with edge
22 strips 332 which are joined together in opposing relation to
23 form a seam 334 extending transversely across the membrane
24 318 between opposite sides of its perimeter 324. A tube
25 opening 336 extends through the seam 334 approximately in
26 the middle thereof and is open at the membrane inner and
27 outer surfaces 320, 322.

28 An adhesive layer 338 substantially covers the membrane
29 inner surface 320 and releasably secures a two-piece
30 protective backing 340 (e.g. paper, plastic or some other

1 conduit for adjustable repositioning. Preferably the band
2 372, in either configuration, forms a relatively fluid-tight
3 seal on the conduit 358. The band 372, like the funnel 362,
4 can be slid through the sheath passage 347 for placement
5 proximal to the sheath distal end 350 (Fig. 15). Belt or
6 tie means 378 can be provided for sealingly fastening the
7 sheath 346 to the band 372. As shown in Fig. 15, the
8 belt/tie means 378 can comprise ligatures 380, which can be
9 wrapped around the sheath 346 for tightening it against the
10 band channel 376. Belt/tie means 378 can comprise other
11 suitable fasteners, such as strips with hook-and-loop
12 fasteners (i.e. fasteners available under the trademark
13 "Velcro"), rubber or elastic bands, plastic coated wire
14 twist ties, etc. Multiple bands 372 can be used for
15 connecting and sealing the sheath 346 and the conduit 358.

16 The conduit distal end can project distally from the
17 sheath distal end 350 (Fig. 15) for connection to tubing 382
18 by a suitable tubing connector, such as the multi-diameter,
19 double male-ended ("Christmas Tree") connector 384 shown in
20 Figs. 11 and 15. The tubing 382 can lead to a suitable
21 fluid collection vessel 386, which can be positioned remote
22 from the patient.

23

24 VII. Applications and Operation

25

26 The fluidic connector 310 can be utilized for a variety
27 of fluidic connection applications without the inner tube or
28 conduit assembly 358. For example, the fluidic connection
29 system 310 can function as a wound dressing which operates
30 in a manner similar to the wound dressings 10, 110 and 210

1 To promote efficient drainage, the connection system
2 310 can be located at a dependent part of a larger dressing.
3 Alternatively, mechanical suction equipment can be connected
4 for promoting drainage.

5 Another application of the fluidic connection system
6 310 is placement over percutaneous catheters, drain tubes,
7 etc. Such tubes present infection risks where they
8 penetrate the skin surface, and can require frequent
9 application of antibiotics to reduce the risk of infection.
10 Percutaneous tubes are often sutured in place at the stab
11 wound locations where they penetrate the skin, and the
12 sutures are further susceptible to infection and can cause
13 swelling and patient irritation. The connection system 310
14 can be placed over such a percutaneous drain tube or
15 catheter site, with the tubing extending through the sheath
16 346 in the manner of the conduit 358. The tubing can be
17 secured, for example with one or more bands 372, to protect
18 against traction forces which might otherwise tend to pull
19 the tubing loose. By utilizing a semi-permeable, breathable
20 material for the membrane 318, the skin surrounding a
21 percutaneous tubing entry site can be protected against
22 maceration.

23 For use as a condom catheter in a urine collection
24 system 312, the backing 340 can be removed from the first
25 panel 328, which is then adhesively secured to the ventral
26 side 389 and the lateral sides 391 of a flaccid penis 388
27 with the urethra orifice or meatus 390 directed at the
28 sheath mouth 356 and the sheath tabs 354 placed on the top
29 and bottom of the glans or penile head 392 (Fig. 13). The
30

1 drain to the funnel 362 for evacuation through the conduit
2 358. Placement and sizing of the sheath 346, the conduit
3 358 and the band 372 can be adjusted to vary the volume of
4 the interstitial space 397.

5 The procedure for applying the connection system 310
6 can be varied according to the conditions of particular
7 patients and the preferences of persons applying it.
8 Properly adhered to a patient, the collection system 310
9 should be functional for a relatively long period of time,
10 and a semi-permeable membrane material can be utilized to
11 enhance patient comfort.

12 Other useful applications of the connection system 310
13 include placement over circumferentially injured limbs and
14 phalanges for draining exudates and/or introducing liquids.
15 For example, an injured hand could be treated by securing
16 the connection system 310 at the wrist, a forearm could be
17 treated by adhering the fluidic connection system 310 at
18 the elbow, etc.

19 Yet another application is for accessory connections
20 whereby various fluid devices and connectors could be
21 combined in systems attached to patients for appropriate
22 treatment and diagnostic procedures. Such additional
23 accessories include Jackson-Pratt and Blake suction tubing
24 devices, Y-connectors, sampling ports, "Injectaport"
25 devices, fluid pumps and various fluid reservoirs. Hand-
26 actuated bulbs could be placed in the tubing, and valving
27 could be placed where it is needed.

28 A further application of the fluidic connection system
29 310 would involve placing the membrane 318 over an
30 intermediate material layer 250 as described in connection

C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. A fluidic connection system, which comprises:
 - (a) covering means with a contact surface and an outer surface;
 - (b) adhesion means for releasably attaching said covering means on said contact surface thereof;
 - (c) said covering means having an interior portion with an opening extending between and open at the contact and outer surfaces thereof; and
 - (d) tube means having a proximate end extending through said opening and terminating adjacent said contact surface and a distal end located outwardly from said outer surface, said tube means fluidically communicating with said contact surface.
2. The invention of Claim 1 wherein said covering means comprises a semi-permeable material.

6. The invention of Claim 2 wherein:

- (a) each said panel includes a perimeter and an edge strip, each said edge strip being demarcated by a fold line and folded outwardly from a remainder of a respective panel; and
- (b) said tube opening extends between said edge strips.

7. The invention of Claim 1 wherein said tube means proximate end includes:

- (a) an opposed pair of longitudinally-extending slits; and
- (b) a pair of opposed end tabs each formed between said slits, said tube means proximate end being open between said tabs.

8. The invention of Claim 7 wherein:

- (a) each said tab is adhesively connected to a respective panel skin contact surface adjacent to said seam.

12. The invention of Claim 11 wherein said tube clamp means comprises:
- (a) an annular band with enlarged proximate and distal ends, a bore extending between said ends and a reduced-diameter waist between said ends, said bore receiving said conduit; and
 - (b) belt means circling said sheath and securing said sheath to said band waist.
13. The invention of Claim 12 wherein:
- (a) said belt means comprises a tensile member wrapped around said sheath and said band waist.
14. The invention of Claim 12 wherein:
- (a) said belt means comprises a strap with hook-and-loop fasteners.
15. A fluidic connection system which comprises:
- (a) covering means including:
 - (1) an inner contact surface;
 - (2) an outer surface;
 - (3) a first panel including a perimeter and an edge;
 - (4) a second panel including a perimeter and an edge;
 - (5) each said panel having an inner contact surface and an outer surface;

16. The invention of Claim 15 wherein said tube means includes:

- (a) an outer, tubular sheath connected to said panels at said seam and having a proximate end, a distal end, and a passage extending between said sheath proximate and distal ends; and
- (b) an inner, tubular conduit extending through said sheath passage and including conduit proximate and distal ends and a conduit bore extending between said conduit ends.

17. The invention of Claim 16 wherein:

- (a) said conduit includes funnel means at its proximate end, said funnel means being adapted to slide longitudinally through said sheath passage.

18. The invention of Claim 16 wherein said tube means includes:

- (a) tube clamp means clamping said sheath to said inner conduit.

20. The invention of Claim 19 wherein said tube means includes:
- (a) opposed pair of longitudinally-extending slits at said proximate end;
 - (b) an opposed pair of tabs formed between said slits, each said tab being adhered to a respective panel inner contact surface; and
 - (c) a mouth open between said tabs at said tube means proximate end.
21. The invention of Claim 20 wherein said tube means includes:
- (a) an outer sheath comprising a flexible, collapsible material and having proximate and distal ends with a passage extending therebetween;
 - (b) an inner, tubular conduit extending through said sheath passage and including conduit proximate and distal ends and a conduit bore extending between said conduit ends;
 - (c) an annular band with enlarged proximate and distal ends and a bore extending between said end, said bore receiving said conduit and a reduced-diameter waist between said ends; and
 - (d) belt means circling said sheath adjacent to its distal end and securing said sheath to said band waist.

24. The method of Claim 22 wherein said step of introducing a liquid to said wound includes irrigating said wound.
25. A method of catheterizing a penis, which comprises the steps of:
- (a) adhering a membrane comprising first and second panels each including a skin contact surface, an outer surface and a perimeter with an edge to the penis;
 - (b) forming a seam with opposite ends and extending transversely across said membrane by adhesively engaging said panel contact surfaces along respective strips adjacent to said edges thereof;
 - (c) providing an opening open at said panel edges and at said contact surface between said interconnected strips and intermediate said seam opposite ends;
 - (d) extending a sheath with a proximate end having an opposed pair of longitudinally-extending slits forming an opposed pair of tabs through said tube opening;
 - (e) positioning a mouth open to a passage of said sheath and formed between said tabs at said seam adjacent to said skin contact surfaces; and

Fig. 1.

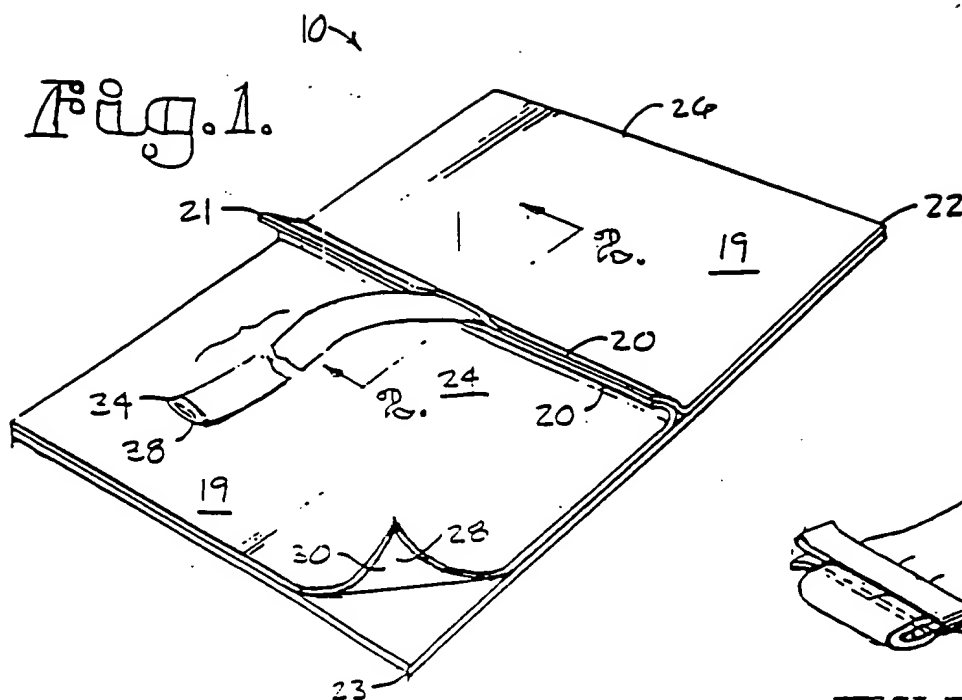


Fig. 5.

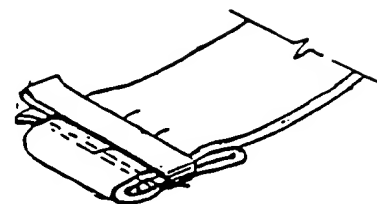


Fig. 2.

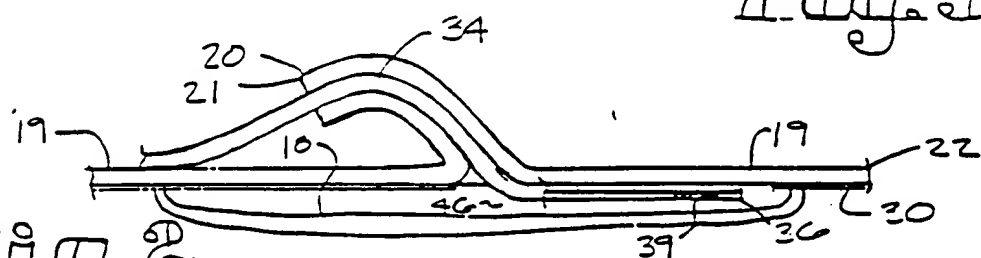


Fig. 3.

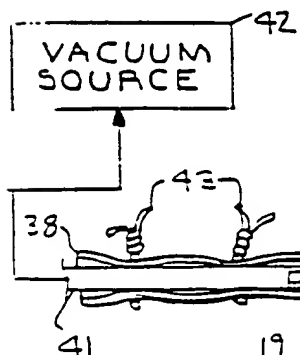
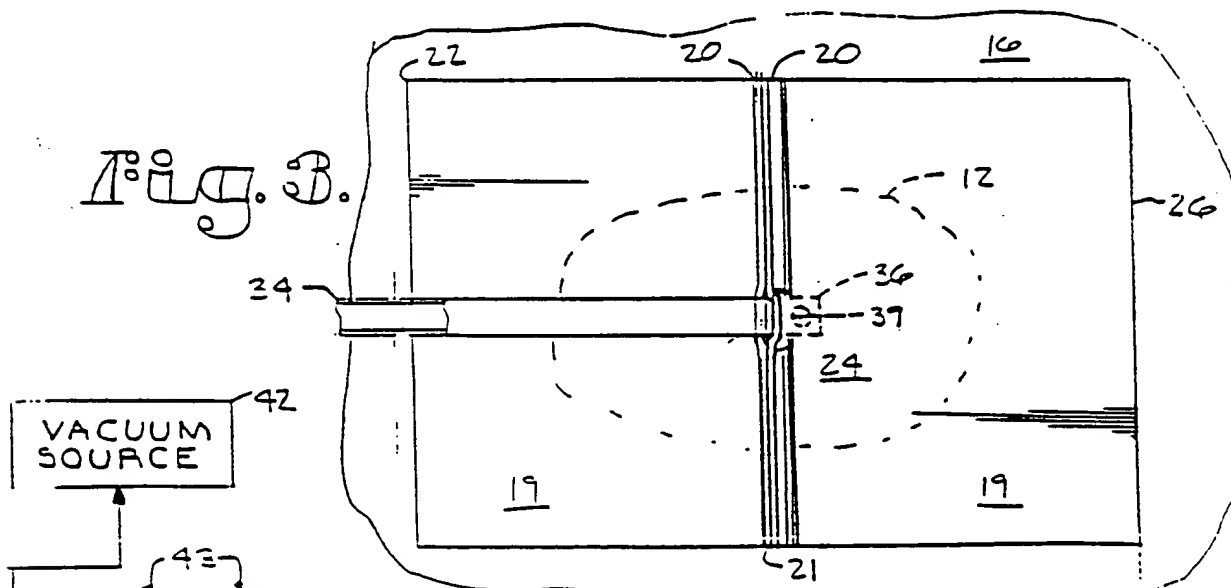


Fig. 6.

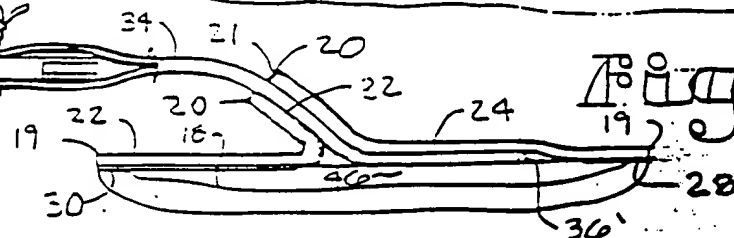


Fig. 11.

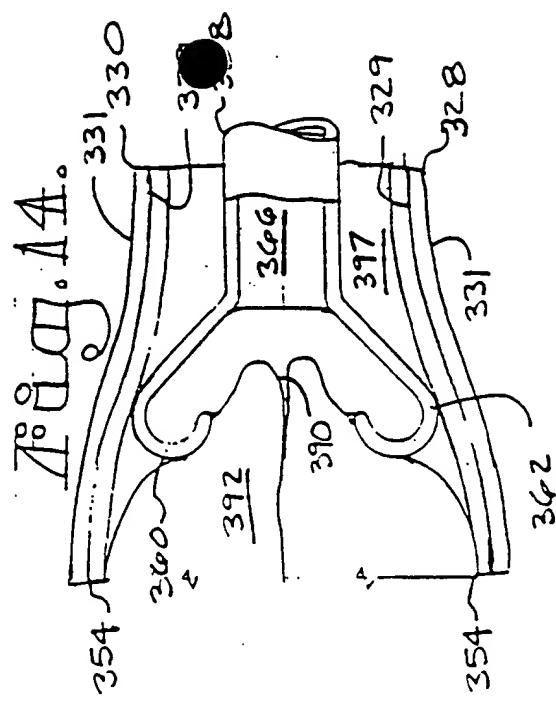
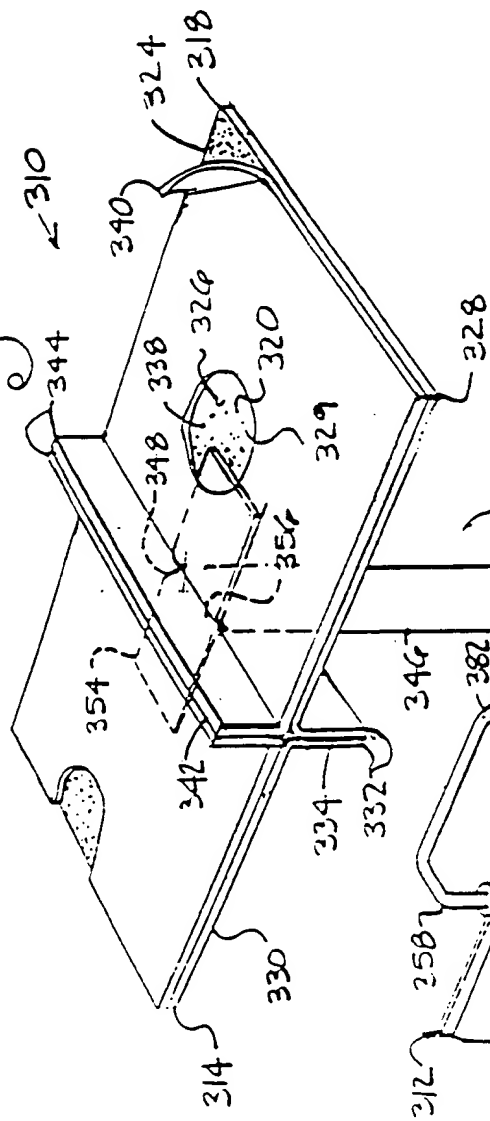
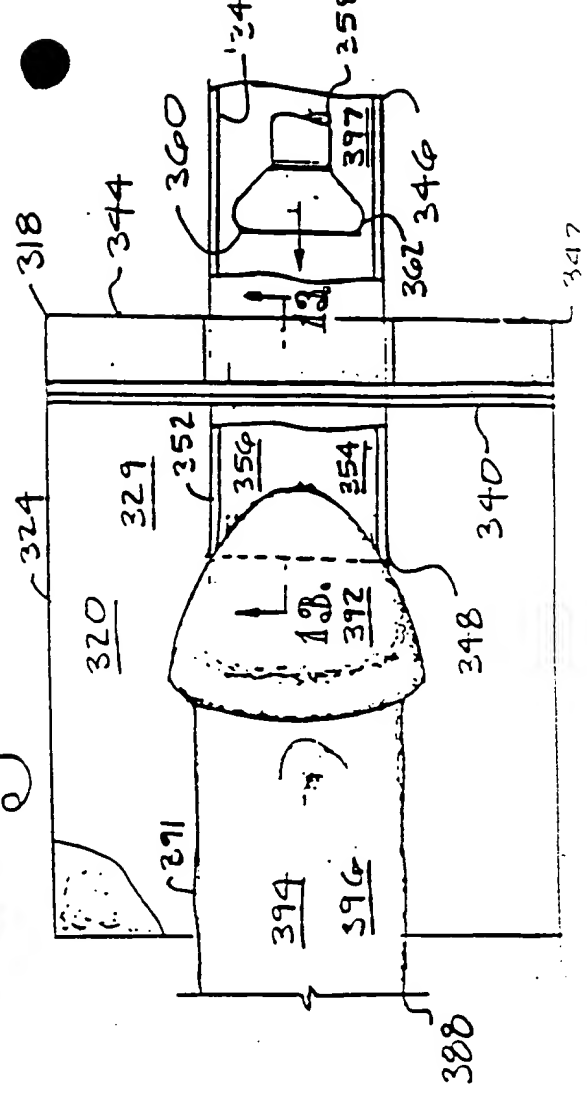
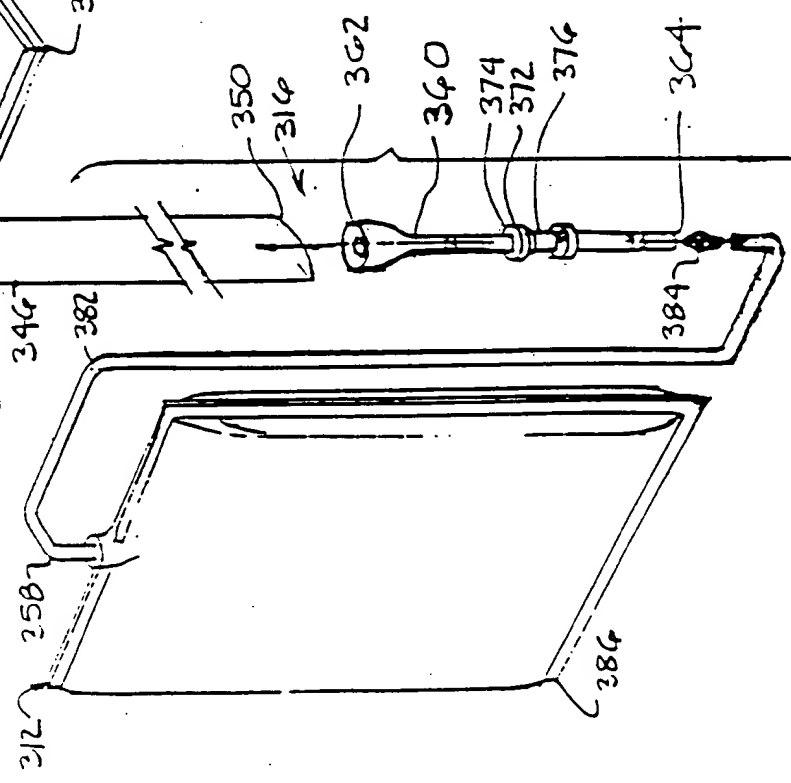


Fig. 12.



INTERNATIONAL SEARCH REPORT

International Publication No. PCT/US90/01777

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ¹

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61M 27/00

U.S. CL: 604/305

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System

Classification Symbols

US

604/174,175,176,179,180,304,305,307,313,
604/346,347,349,353 128/842,844Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁴III. DOCUMENTS CONSIDERED TO BE RELEVANT ^{1*}

Category [*]	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
Y	US, A, 3,367,332 (GROVES) 06 February 1968 see entire document	1-24
Y	US, A, 4,080,970 (MILLER) 28 March 1978 see entire document	1,2,4,7,11 14,16,18,22-24
Y	US, A, 3,682,180 (McFARLANE) 08 August 1972 see entire document	1-18
A	US, A, 4,743,232 (KRUGER) 10 May 1988 see entire document	1-18,22-24
A	US, A, 4,525,166 (LECLERC) 25 June 1985 see entire document	1-18,22-24
A	US, A, 4,543,100 (BRODSKY) 24 September 1985 see entire document	1-18,22-24
Y	US, A, 4,373,519 (ERRESE ET AL.) 15 February 1983 see entire document	8,10,13,17
Y	US, A, 4,475,909 (EISENBERG) 09 October 1984 see entire document	25-28
A,P	US, A, 4,838,883 (MATSUURA) 13 June 1989 see entire document	25-28
A,P	US, A, 4,863,449 (THERIAULT ET AL.) 05 September 1989 see entire document	25-28

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-O- document referring to an oral disclosure, use, exhibition or other means

-P- document published prior to the international filing date but later than the priority date claimed

-T- later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

-X- document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

-Y- document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

-3- document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search: ²

21 MARCH 1990

International Searching Authority ¹

ISA/US

Date of Mailing of this International Search Report ³

06 AUG 1990

Signature of Authorized Officer ¹⁰

KATHLEEN A. DALEY

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